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10/526,837	10/26/2005	Dusan Miljkovic	101267.0044US	1088

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EXAMINER	
MCCORMICK, MELENIE LEE	
ART UNIT	PAPER NUMBER
1655	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,837	MILJKOVIC ET AL.	
	Examiner	Art Unit	
	Melenie McCormick	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 04/2005.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-17 are presented for examination on the merits.

Claim Objections

Claim 1-17 are objected to because of the following informalities: It appears that the word "adenosine" has been omitted in claim 1. Because AMPK stands for adenosine 5'-monophosphate-activated protein kinase, the word "adenosine" should be placed in front of the number 5 in line 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 -17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' claims are drawn to a method which comprises administering to a patient a composition which comprises a compound that activates AMPK, wherein the compound that activates AMPK has the structure of a compound purified from an

extract of barley malt (see e.g. claims 1 and 10). Thus, the claims are drawn to a method of using a compound that is defined only by its function.

To provide adequate written description and evidence of possession of a claimed compound, the specification must provide sufficient distinguishing identifying characteristics of the compound. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factor present in the claims is drawn to slight structural limitation (that the compound has the structure of a compound that is purified from an extract of barley malt) and a functional limitation (that the compound activates AMPK), which is not a description of the actual structure of the compound. The specification discloses that the term " a compound that activates adenosine 5'-monophosphate-activated protein kinase (AMPK)" refers to any compound or mixture of compounds that, when placed in contact with an appropriate cell or organism, increases the rate at which AMPK phosphorylates any one of a number of its protein targets (see e.g. page 5, lines 22-25). This disclosure merely provides one functional characteristic of the compound. The specification fails to describe the structure of even one compound which would have this effect and the skilled artisan cannot envision the structure of the inhibitor based upon its function. Accordingly, in the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed compound which activates AMPK.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the claimed compound, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, the full breadth of the claims does not meet the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 10, at lines 5-6, the phrase "has the structure of a compound purified from an extract of ground barley malt" renders the claim vague and indefinite. It is not clear if the compound is actually purified from an extract of ground barley malt or not.

In claim 3, at line 2, the term "obtainable" renders the claim vague and indefinite. It is not clear if the compound purified from an extract of ground barley malt is actually obtained through the purification process described, or if it is merely possible to obtain the compound in this manner.

In claims 4, and 5, at line 1, the phrase "thaumantin-like protein" renders the claim vague and indefinite. The phrase "thaumantin-like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed, thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

In claim 12, at line 2, the term "obtainable" renders the claim vague and indefinite. It is not clear if the compound purified from an extract of ground barley malt

is actually obtained through the purification process described, or if it is merely possible to obtain the compound in this manner.

Claim 17 recites the limitation "the same structure as the compound recited in claim 16" in line 2. There is insufficient antecedent basis for this limitation in the claim because claim 16 does not provide a structure for the compound that activates AMPK.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 17 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 10/469,384 and claims 1, 5-8, and 15-17 of copending Application No 10/220,761. Although the conflicting claims are not identical, they are not patentably distinct because each are drawn to a composition comprising a compound isolated from barley malt (Hordeum vulgare) and a method of treatment using a compound. Further, the claims of '384 and '761 encompass and/or are encompassed by the instant claims.

This is a provisional obvious-type double patenting rejection because the conflicting claims have in fact not been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hejgaard et al. (FEBS).

A process for purifying from an extract of ground barley malt a composition comprising a compound that activates AMPK, wherein the process comprises

fractionating the extract of ground barley malt by ion exchange chromatography into protein fractions, collecting one or more protein fractions, and removing protein from the protein fractions by molecular sieving chromatography to result in a purified compound is claimed.

Hejaard et al. teach a method of protein purification using seeds of barley (Hordeum vulgare) (see e.g page 127, Materials and Methods 2.1). Hejaard et al. further teach that the method includes the step of separating (fractionating) using cation exchange chromatography, collecting the protein appearing in the first peak, and applying this to a Sephadex G50 column (which reads on molecular sieve chromatography, as instantly claimed) (see e.g. page 128, 2.3 Purification). This would remove proteins and result in a composition comprising the compound instantly claimed. Although Hejaard et al. may not explicitly teach that the composition is obtained from malted barley extract, it is assumed that the composition would, nonetheless, inherently comprise the compound as instantly claimed since it was obtained from a barley extract. Please note that even though Hejaard et al. do not explicitly teach that the composition obtained using this method activates AMPK, the compound would inherently have this functional characteristic, since was obtained in the same manner as instantly claimed.

Therefore, the reference is deemed to anticipate the instant claims above.

Claims 1-5, 8-12 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hsai et al. (US 6,270,774).

A method for activating AMPK in a patient in need thereof, wherein the method comprises administering to said patient a composition comprising a therapeutically effective amount of a compound that activates AMPK, wherein the compound has the structure of a compound purified from an extract of barley malt is claimed.

Hsai et al. teach the administration of a composition which comprises barley grass extract (see e.g. claim 1). Hsai et al. further teach that the composition was administered to subjects with abnormal lipid profiles (i.e. in need of AMPK regulation) (see e.g. col 16, lines 42-45). Hsai et al. further teach that the composition is effective in lowering blood sugar levels (see e.g. col 4, lines 24-27). Hsai et al. further teach that the composition elevates levels of high density lipoprotein (HDL) (see e.g. claim 1). Please note that because the composition taught by Hsai et al. contains a barley extract, it also, therefore, contains a compound which has the structure of a compound purified from an extract of barley malt, as instantly claimed.

Please note that, although Hsai et al. do not explicitly teach that the composition containing barley extract was obtained in the same manner as instantly claimed, it is, nonetheless, a barley extract composition. The composition taught by Hsai et al. would, therefore, inherently provide the functional characteristics upon administration. Please also note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' barley malt extract composition differs and, if so, to what extent, from that of the discussed reference. Therefore, with the showing of the reference, the burden of establishing that the

reference does not anticipate the claimed invention by objective evidence is shifted to the Applicants.

Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsai et al. (US 6,270,774) in view of Kannel (Am Heart Journal- Abstract).

A method for activating AMPK in a patient in need thereof, wherein the method comprises administering to said patient a composition comprising a therapeutically effective amount of a compound that activates AMPK, wherein the compound has the structure of a compound purified from an extract of barley malt is claimed.

Hsai et al. beneficially teach the administration of a composition which comprises barley grass extract and is relied upon for the reasons set forth above. Hsai et al. do not explicitly teach the administration of the composition to subjects suffering from diabetes (glucose intolerance) or obesity.

Kannel beneficially teaches that diabetics show abnormal blood lipid profiles and that reduced levels of high density lipoproteins (HDL) are associated with both diabetes and obesity (see e.g. Abstract).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer a composition which comprises a compound having the structure of a compound purified from an extract of barley malt in order to treat a condition which is regulated by AMPK (such as diabetes/elevated blood glucose or low levels of HDL) based upon the beneficial teaching of Hsai et al. that such a composition has been administered to subjects with the same conditions as instantly claimed (i.e. those in need of elevation of HDL and reduction of glucose). One of ordinary skill in the art at the time the claimed invention was made would have been motivated and would have had a reasonable expectation of success in doing so based upon the beneficial teaching of Hsai et al. that administration of this composition resulted in significant increases in HDL levels and a significant decrease in levels of blood glucose (see e.g. col 16, lines 60-67- col 17, lines1-5). Administration of the composition of Hsai et al. to subjects suffering diabetes or obesity would also have been obvious to one of ordinary skill in the art at the time the claimed invention was made because, as taught by, Kannel (Am Heart Journal- Abstract), abnormal blood lipids and low HDL are conditions associated with diabetes and obesity. Although the additional functional effects instantly claimed are not explicitly taught by Hsai et al., these effects would intrinsically occur upon administration of a composition which comprises a compound which has a structure of a compound purified from barley malt, as taught by

Hsai et al. This is particularly true because the composition is administered to individuals with the same conditions (i.e. elevated blood glucose and elevated HDL levels).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie McCormick whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TERRY MCKELVEY, PH.D.
SUPERVISORY PATENT EXAMINER